REMARKS/ARGUMENTS:

Specification

Applicants have amended the first full paragraph on page 13 to clarify the "altering means" and the "means for conducting electrical energy" in the specification.

CLAIM REJECTIONS -35 USC § 102

The Examiner stated that claims 31-32, 34-35, 37-38, 46-47, 53, 61,64-68,74,82 and 85-88 are rejected under 35 U.S.C. 102(a) or (c) as being anticipated by Brown III, et al. (US 6,219,577).

In making this conclusion, the Examiner stated that Brown, Ill et al. discloses an iontophoresis, electroporation and combination catheter for local drug delivery to arteries and other body tissues, comprising, a catheter (10) having distal end (14), a proximal end (12), and an iontophoretic transport means (24), the catheter having one lumen (see Figure 3) or more lumens (see Figure 4); a cylindrically shaped expansion member (20) coated or impregnated with a drug or other therapeutic agent positioned on the distal end of the catheter, the cylindrically shaped expansion member having a first contracted diameter (see Figure 1) and a second expanded diameter (see Figure 2), the second expanded diameter being larger than the first contracted diameter; see Column 8, lines 13-27, column 9, lines 1-26; Column 10, lines 13-17 and hues 35-68; Column 11, lines 22-63; column 14, lines 11-68; and Column 15, lines 1-22and lines 62-63.

Response:

The Brown III, et al. patent discloses several embodiments of catheter designs to be used for the prevention of restenosis following angioplasty in arteries and treatment of other organs using iontophoresis and electroporation. One embodiment that is the most relevant to the Applicant's present invention comprises a catheter with a distal end composed of flexible individual wire electrodes (expandable tubular braided sleeve, column 9, lines 4-5) which are mounted around and parallel to the longitudinal axis of the catheter body (column 9, lines 5-6). When located in the body the electrodes, 24, can be mechanically expanded and the middle region of the expanded electrodes are closely juxtaposed to the tissue to be treated (column 9, lines 16-19). Only the middle region of the electrodes is coated with a visco-elastic polymer matrix incorporating drug or other therapeutic agents (column 9, lines 20-22). The electrodes may be alternated with polyester monofilaments, also in a parallel arrangement to the catheter body, to provide structural support (column 9, lines 44-46).

The catheter of the above invention may be used after the sequence of balloon dilatation has been completed and the balloon is withdrawn (column 6, lines 24-26). Alternatively, the catheter may be us before balloon dilatation (column 6, lines 33-36).

In another embodiment of the catheter, the polymer matrix containing the drug may be molded into a short tubular expandable visco-elastic sleeve which fits over the middle region of the electrode array.

There are several physical and functional features of the Applicant's present invention which distinguishes it from the Brown III et al disclosure. These physical and functional features of the Applicant's present invention also will provide clinical

applications and advantages that are neither claimed nor disclosed in the Brown III et al. patent.

First, the electrodes of the Brown III et al. invention are oriented "parallel to the catheter body". This is an essential feature of the Brown III et al. invention for it is what allows "the electrodes to lie substantially flat when the electrodes are in a relaxed position" (Brown III et al. Claim 1, lines 31-32). The Applicant respectfully disagrees with the Examiner in that the Brown III et al. device does not disclose or claim a cylindrically shaped expansion member (20). Rather the distal end is arcuate when the electrodes are in an expanded configuration.

The distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Brown III et al. invention, only the middle portions of the wire elements contact the tissue. This is due to the arcuate nature of the electrodes which are also parallel to the catheter body. Brown II et al. does not disclose or teach the definition of a cylinder because the electrodes have a continual sloping or arcing perpendicular distance R along the axis Z (see "Spherical Polar Coordinates" example in Exhibit A). The Applicant's invention discloses and claims that the distal mesh is cylindrically shaped to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member upon expansion. The Applicants' invention has an expansion member that has a relatively constant perpendicular distance R along the central axis Z and therefore a constant surface (see "Cylindrical Coordinate Examples" in Exhibit A).

The functional polymer coating of the electrodes of the Brown III et al. invention are only in the middle sections of the electrodes because this is the section that contacts the vessel walls which compromises a rather small portion of the total length of the arcuate electrodes. In contrast, the cylindrical dilating member of the Applicant's invention maximizes contact with the surface area for a treatment site that occurs substantially along the length of the distal expanded member. In *Ad-in-the-Hole v Hageman*, Civ. App. 96-1455 (Fed. Cir. Apr. 2 1997), the Federal Circuit affirmed that a cylinder shape invention was not equivalent to a donut or toroidal shape for a golf club advertising invention. Likewise, and even more importantly, the arcuate electrodes of the Brown III et al. device are not equivalent to the Applicants' cylindrically configured dilating member.

Furthermore, the significance of the Applicant's design is clinically distinguishable from the Brown III et al. design. For example, a comparison between the present invention and the Brown III et al. invention for treating a typical 10 - 15 mm length lesion site exemplifies the distinguishable advantages of the Applicants' present invention. To achieve the equivalent exposure to and delivery of a medicament that the Applicants' present invention accomplishes in a single expansion/delivery (10 - 15 mm) operation, the limited "middle" contact area of Brown III et al. with the arcuate design would require the use of multiple devices to cover the 10 – 15 mm length. The use of multiple devices would include a plurality of device retractions and device advancements to treat the 10 – 15 mm length. Multiple insertions and retractions of Brown III et al. devices would greatly complicate the clinical procedure and increase the risk to the patient. For example, as one Brown III et al. device is deployed within a treatment site, it would have to be retracted and replaced with another device (since the medicament would be depleted from the contact area of the electrode). Using typical radiographic techniques, positioning the "new" Brown III et al. device such that its contact area is adjacent to the previous

treated area would be extremely difficult and the end result has a high probability of variable administration of medicaments along a lesion segment. Also, it is well understood by one skilled in the art that it is not trivial to insert and retract multiple interventional devices within the human vasculature. There is always the potential for damage to intimal and medial layers of the vascular pathway subjected to an advancement or retraction of a interventional device, and multiple advancements and retractions of the Brown III et al. device increases the risk of the clinical procedure. Furthermore, acute complications, such as dissections and perforations are known to occur and multiple advancement and retractions of the Brown III et al. devices also increases the risk of these complications.

In addition, the Applicant's wire mesh does not lie substantially flat against the catheter body when in a relaxed position.

Lastly, and likely as important as the other distinguishing features presented herein, the Brown III et al. invention discloses that is to be used either following or prior to a balloon angioplasty procedure. The design of the distal electrodes does not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. Conversely, as disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Application's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel.

Accordingly, Applicant respectfully submits that the claims 31-32, 34-35, 37-38, 46-47, 53, 61, 64-68, 74, 82 and 85-88, are patentably distinguishable over Brown III et al. Withdrawal of this rejection is respectfully requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner has rejected Claims 33 and 36 under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577) in view of Gencheff et al. (US5,423,744).

In making this conclusion, the Examiner stated Brown, Ill et al. discloses the invention as claimed with the exception of the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire.

The Examiner stated that Gencheff et al. discloses a catheter system for the deployment of biological material, as shown in Figures 7-10, comprising the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire, see Column 10, line 60 through Column II, line 20, It would have been obvious to one having ordinary skill in tile art to have modified Brown, Ill et al,'s disclosed method of use with the added steps of positioning a guidewire in the body passageway, and threading the expansion member over the guidewire, so as to more effectively control placement of the device at the treatment site.

Response:

First, Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

As the Applicant previously asserted, and summarized below, the electrodes of the Brown III et al. designed invention is oriented "parallel to the catheter body". In contrast, the distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Brown III et al. invention, only the middle portions of the wire elements contact the tissue (See Figure 10) due to the arcuate nature of the electrodes which are parallel to the catheter body.

The Applicant's present invention, the distal mesh is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member when expanded. Therefore any coating of the electrodes of the Brown III et al. invention are only in the middle sections of the electrodes because of the arcuate shape of the "conductors" is the section that contacts the vessel walls. The entire cylindrical dilating member of our invention is coated with drug containing to maximize the contact surface and delivery area.

In addition, the Brown III et al. invention discloses that is to be used either following or prior to a balloon angioplasty procedure. The design of the distal electrodes does not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. Conversely, as disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Application's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel.

The Applicants assert that the addition of Gencheff et al. guidewire does not overcome the distinguishing features of Brown III et al.

Lastly, the Applicants assert that one of the primary element of establishing a prima facie case of obviousness it that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." The Applicants declare that there is no suggestion or motivation from the cited prior art to combine these references.

Accordingly, Applicant respectfully submits that the claims 33 and 36 are patentably distinguishable over Brown III et al. Withdrawal of this rejection is respectfully requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner has rejected Claim 45 under U.S.C. 103(a) as being unpatentable over Brown III et al. (US 6,219,377 B1) in view of Dubrul et al. (US 6,450,989).

The Examiner stated that Brown III et al, discloses the invention as claimed with the exception of the cylindrically shaped expansion member comprising a first plurality of flexible elongate elements helically wound in a first direction or rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

The Examiner stated that Dubrul et al. discloses a dilating and support apparatus comprising a dilation mechanism (9), as depicted in Figures 4-A and 4-B,

made of an open, mesh metal braid, which allows for perfusion therethrough and is formed by a "Maypole" dance of filament carriers to create a zigzag pattern, wherein one filament moves helically clockwise and the other moves helically counter-clockwise, see Column 13, line 35 through Column 14, line 28; Column U, lines 30-31; and Column 21, line 4 through Column 22, line 55.

The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown. Ill et al's cylindrically shaped expansion member with an open, mesh braid as taught by Dubrul et al. so as to increase the amount of surface area of the device in contact with the vessel wall thereby enabling more controlled and accurate delivery of medicament to affected wall tissue.

<u>Response:</u>

First, Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

As the Applicant previously asserted, and summarized below, the electrodes of the Brown III et al. designed invention is oriented "parallel to the catheter body". In contrast, the distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Brown III et al. invention, only the middle portions of the wire elements contact the tissue (See Figure 10) due to the arcuate nature of the electrodes which are parallel to the catheter body.

The Applicant's present invention, the distal wire mesh is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member when expanded. Therefore any coating of the electrodes of the Brown III et al. invention with liposomes would occur only in the middle sections of the electrodes because of the arcuate shape of the "conductors" is the only section that contacts the vessel walls. Dubrul et al. suffer from the same inefficient delivery design as Brown. Referring to Figures 4B and 5B, the expanded Dubrul et al. does not attain the cylindrically shaped expansion member of the Applicant's present invention but rather is arcuate in shape. Upon expansion of the Dubrul invention, only the middle portions of the braided mesh would contact the tissue (See Figures 4B and 5B) due to the arcuate nature of the mesh (also see Exhibit A) .

In addition, the Brown III et al. invention discloses that is to be used either following or prior to a balloon angioplasty procedure. The design of the distal electrodes does not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. Conversely, as disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Application's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel.

Lastly, the Applicants assert that one of the primary element of establishing a prima facie case of obviousness it that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching

suggestion or incentive supporting the combination." The Applicants declare that there is no suggestion or motivation from the cited prior art to combine these references.

Accordingly, Applicant respectfully submits that the claim 45 is patentably distinguishable over Brown III et al. in view of Dubrul et al. Withdrawal of this rejection is respectfully requested.

<u>CLAIM REJECTIONS -35 USC § 103</u>

The Examiner stated that Claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577) in view of Segal et al. (US 5,034,001).

The Examiner stated that Brown, Ill et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like. The Examiner stated that Segal discloses a vascular dilatation device for localized delivery of heparin, TPA, hirudin or various anti-thrombin agents, see Column 10, lines 55-61. The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown, Ill et al.'s catheter for local drug delivery with heparin delivery as taught by Segal, so as to prevent clotting of the blood adjacent the dilation device.

<u>Response:</u>

Applicant is incorporating by reference the arguments made above (Claim Rejection-35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

As the Applicant previously asserted, and summarized below, the electrodes of the Brown III et al. designed invention is oriented "parallel to the catheter body". In contrast, the distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Brown III et al. invention, only the middle portions of the wire elements contact the tissue (See Figure 10) due to the arcuate nature of the electrodes which are parallel to the catheter body.

The Applicant's present invention, the distal wire mesh is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member when expanded. Any coating of the electrodes of the Brown III et al. invention occurs only in the middle sections of the electrodes because of the arcuate shape and therefore the "conductors" is the middle section that contacts the vessel walls. The entire cylindrical dilating member of our invention is coated with drug containing to maximize the contact surface and delivery area.

In addition, the Brown III et al. invention discloses that is to be used either following or prior to a balloon angioplasty procedure. The design of the distal electrodes does not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. Conversely, as disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Application's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel.

Lastly, the Applicants assert that one of the primary element of establishing a prima facie case of obviousness it that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." The Applicants declare that there is no suggestion or motivation from the cited prior art to combine these references.

The addition of using heparin, TPA, hirudin or various anti-thrombin agents of Segal does not overcome the distinguishing features and inefficient design of the Brown III et al. invention and therefore does not allow the Brown III et al. invention to either anticipate or make the Applicants' present invention obvious.

Accordingly, Applicant respectfully submits that the claims 48, 49, 69 and 70 are patentably distinguishable over Brown III et al. in view of Segal et al. Withdrawal of this rejection is respectfully requested.

<u>CLAIM REJECTIONS -35 USC § 103</u>

The Examiner stated that claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown Ill et al. (US 6,219,577 BI) in view of Tsugita (US 6,142,987 A). The Examiner reasoned that Brown, Ill et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like. The Examiner explained that Tsugita discloses an endovascular filter device coated with heparin and heparinoids, see Columns, lines 31-33. The Examiner concluded that it would have been obvious to one having ordinary skill in the art to have modified Brown, Ill et al. cylindrically shaped expansion member with a

heparin/heparinoid coating taught by Tsugita, so as to reduce thrombi formation of the flexible elongate elements which comprise the expansion member thus ensuring adequate sustained perfusion therethrough.

Response:

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

As the Applicant previously asserted, and summarized below, the electrodes of the Brown III et al. designed invention is oriented "parallel to the catheter body". In contrast, the distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Brown III et al. invention, only the middle portions of the wire elements contact the tissue (See Figure 10) due to the arcuate nature of the electrodes which are parallel to the catheter body.

The Applicant's present invention, the distal wire mesh is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member when expanded. Any coating of the electrodes of the Brown III et al. invention occurs only in the middle sections of the electrodes because of the arcuate shape and therefore the "conductors" is the middle section that contacts the vessel walls. The entire cylindrical dilating member of our

invention is coated with drug containing to maximize the contact surface and delivery area.

In addition, the Brown III et al. invention discloses that is to be used either following or prior to a balloon angioplasty procedure. The design of the distal electrodes does not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. Conversely, as disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Application's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel.

The addition of using anti-coagulant agents such as heparin or heparinoids of Tsugita does not overcome the distinguishing features and inefficient design of the Brown III et al. invention and therefore does not allow the Brown III et al. invention to either anticipate or make the Applicants' present invention obvious.

Lastly, the Applicants assert that one of the primary element of establishing a prima facie case of obviousness it that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." The Applicants declare that there is no suggestion or motivation from the cited prior art to combine these references.

Accordingly, Applicant respectfully submits that the claims 48, 49, 69 and 70 are patentably distinguishable over Brown III et al. in view of Tsugita. Withdrawal of this rejection is respectfully requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner has stated that claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, Ill et al. (US 6,219,577 B1) in view of Lennox (US 6,280,411 BI), Palasis et al. (US 6,369,039 BI), or Naimark et al. (US 6,638,246 BI).

In making this conclusion, the Examiner stated that Brown III et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 50-52, 54-58, 62, 63, 71-79, 83 and 84. Lennox (Column 4, line 22 through Column 5, line 35), Palasis et al. (Column 4, line 64 through Column 6, line 22), and Naimark et al. (Column 8, line 50 through Column 10, line 23), all individually, discloses a device for localized delivery of drug agents comprising an expansion member (210, 120, l0/20N208/30/40N408/ 50/60/80A/80B, respectively) coated with a medicament comprising a promoter of vascular cell growth, a transcriptional activator, an inhibitor of vascular cell growth, a growth factor receptor antagonist, a cholesterol-lowering agents, a vasodilating agent, an agent that interferes with endogenous vasoactive mechanisms. estrogen, a smooth muscle inhibitor, a compound that inhibits cellular proliferation, and paclitaxel.

The Examiner reasoned that it would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Lennox, Palasis et al., or Naimark et al.,

so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

Response:

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

As the Applicant previously asserted, and summarized below, the electrodes of the Brown III et al. designed invention is oriented "parallel to the catheter body". In contrast, the distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Brown III et al. invention, only the middle portions of the wire elements contact the tissue (See Figure 10) due to the arcuate nature of the electrodes which are parallel to the catheter body.

The Applicant's present invention, the distal wire mesh is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member when expanded. Any coating of the electrodes of the Brown III et al. invention occurs only in the middle sections of the electrodes because of the arcuate shape and therefore the "conductors" is the middle section that contacts the vessel walls. The entire cylindrical dilating member of our invention is coated with drug containing to maximize the contact surface and delivery area.

In addition, the Brown III et al. invention discloses that is to be used either following or prior to a balloon angioplasty procedure. The design of the distal electrodes does not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. Conversely, as disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Application's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel.

The addition of using the drugs (promoter of vascular cell growth, a transcriptional activator, an inhibitor of vascular cell growth, a growth factor receptor antagonist, a cholesterol-lowering agents, a vasodilating agent, an agent that interferes with endogenous vasoactive mechanisms. estrogen, a smooth muscle inhibitor, a compound that inhibits cellular proliferation, and paclitaxel) of Lennox, Palasis et al., or Naimark et al. do not overcome the distinguishing features and inefficient design of the Brown III et al. invention and therefore does not allow the Brown III et al. invention to either anticipate or make the Applicants' present invention obvious.

Lastly, the Applicants assert that one of the primary element of establishing a prima facie case of obviousness it that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." The Applicants declare that this is no suggestion or motivation from the cited prior art to combine these references.

Accordingly, Applicant respectfully submits that the claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 are patentably distinguishable over Brown III et al. in view of Lennox, Palasis et al., or Naimark et al. Withdrawal of this rejection is respectfully requested.

CLAIM REJECTIONS -35 USC § 103

The Examiner stated that claims 59, 60, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, Ill et al. (US 6,219,577 B1) in view Hanson et al. (US 5,985,307A). Brown, III et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 59, 60, 80 and 81.

The Examiner reasoned that Hanson et al, (Column 18, line 50 through Column 19, line 339 and Column 26, line 62 through Column 27, line 3) discloses a device for localized delivery of drug agents comprising an expansion member (50) containing a medicament comprising an agent that modulates intracellular calcium binding proteins, and a receptor blocker for contractile agonists.

In making this conclusion, the Examiner stated that it would have been obvious to one having ordinary skill in the art to have modified Brown, Ill et al's cylindrically shaped expansion member with a variety of drugs as taught by Hanson et al., so as to enable treatment of a variety of conditions including localized disease and/of vessel occlusion.

Response:

Applicant is incorporating by reference the arguments made above (Claim Rejection- 35 USC § 102) that distinguished significant elements of the Brown III et al. device from the Applicant's present invention.

As the Applicant previously asserted, and summarized below, the electrodes of the Brown III et al. designed invention are oriented "parallel to the catheter body". In contrast, the distal wire mesh of Applicant's present invention is a circumferentially braided wire mesh which is not oriented parallel to the catheter body. Furthermore, when expanded, the distal wire mesh of the Applicant's present invention does not have a series of arcuate shaped electrodes but rather comprises a cylindrically shaped expansion member. Upon expansion of the electrodes of the Brown III et al. invention, only the middle portions of the wire elements contact the tissue (See Figure 10) due to the arcuate nature of the electrodes which are parallel to the catheter body.

The Applicant's present invention, the distal wire mesh is cylindrically shaped (as disclosed and claimed) to provide maximum tissue contact along the entire length of the cylindrically shaped expansion member when expanded. Any coating of the electrodes of the Brown III et al. invention occurs only in the middle sections of the electrodes because of the arcuate shape and therefore the "conductors" is the middle section that contacts the vessel walls. The entire cylindrical dilating member of our invention is coated with drug containing to maximize the contact surface and delivery area.

In addition, the Brown III et al. invention discloses that is to be used either following or prior to a balloon angioplasty procedure. The design of the distal

electrodes does not have the capability of generating the radial forces necessary to dilate the blood vessel or organ. Conversely, as disclosed and claimed in the present invention application, the circumferentially oriented wire braid of the Application's invention is designed to generate sufficient radial forces upon expansion to dilate or further enhance a previously dilated diseased segment in a blood vessel.

The addition of using a medicament comprising an agent that modulates intracellular calcium binding proteins, or a receptor blocker for contractile agonists of Hansen does not overcome the distinguishing features and inefficient design of the Brown III et al. invention and therefore does not allow the Brown III et al. invention to either anticipate or make the Applicants' present invention obvious.

Lastly, the Applicants assert that one of the primary element of establishing a prima facie case of obviousness it that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination." The Applicants declare that this is no suggestion or motivation from the cited prior art to combine these references.

Accordingly, Applicant respectfully submits that the claims 59, 60, 80 and 81 are patentably distinguishable over Brown III et al. in view of Hanson et al. Withdrawal of this rejection is respectfully requested.

Based on the foregoing, Applicant respectfully submits that the application now is in condition for prosecution and allowance. If any matters can be resolved by telephone, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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